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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/702,114	08/23/96	IBEA	M 1912-0151P

18M2/1125
BIRCH STEWART KOLASCH AND BIRCH
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FALLS CHURCH VA 22040-0747

EXAMINER

GUPTA, A

ART UNIT	PAPER NUMBER
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1811

476

DATE MAILED:

11/25/97

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks



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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

DATE MAILED:

☒ This application has been examined ☒ Responsive to communication filed on 9-16-97 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 MONTHS from the date of this letter.
Failure to respond within the time period will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENTS ARE PART OF THIS ACTION:

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449 | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-20 are pending in the application.
Of the above claims, ____ are withdrawn from consideration.
2. ☐ Claims ____ have been cancelled.
3. ☐ Claims ____ are allowed.
4. ☒ Claims 1-20 are rejected.
5. ☐ Claims ____ are objected to.
6. ☐ Claims ____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____ has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under 35 USC 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. ____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

08/702,114

DETAILED ACTION

***Claim Rejections - 35 USC § 112
Second Paragraph***

1. In view of applicants amendments, this rejection is withdrawn.

Claim Rejections - 35 USC § 102

2. This rejection is hereby withdrawn.

Claim Rejections - 35 USC § 103

3. Claim 1-11, 13-14, and 18-19 remain and newly added claim 20 is rejected under 35 U.S.C. § 103 as being unpatentable over Gaudreau et al. in view of Coy et al. in further view of Felix et al.
4. Claims 1 and 12 remain rejected under 35 U.S.C. § 103 as being unpatentable over Bercu in view of Gaudreau et al. or Coy et al.
5. Claims 1 and 16 remain rejected under 35 U.S.C. § 103 as being unpatentable over Gaudreau et al. in view of Kann et al.
6. Claims 1 and 15 remain rejected under 35 U.S.C. § 103 as being unpatentable over Gaudreau et al. in view of Recker.
7. Claims 1 and 17 remain rejected under 35 U.S.C. § 103 as being unpatentable over Gaudreau et al. in view of Clark.

All of the rejection are maintained for the reasons set forth in the previous office action dated 6-19-97 and the reasons set forth below.

The claims are drawn to GRF peptides that have N-terminal modification in the form of hydrocarbon chain elongation of the N-terminus.

Applicants argue that compounds containing a double bond and having linear main chain length of 5 to 7 carbons possess unexpected and obvious properties over those of alkane. Applicants further state that in neither

references of Coy et al. or Gaudreau et al. is there any suggestion of alkene based compounds having 5 to 7 carbons or of the superior activity possessed thereby since the reference only disclose alkane based compounds of 3, 4, 6, or 8 carbons.

Applicant's arguments and the Declaration by Dr. Brazeau filed 9-16-97 have been fully considered but they are not persuasive.

First, as indicated in the previous office action, the reference teach that a substitution having 4-8 carbon atoms was effective in increasing the hydrophobicity of the peptide and induce GH secretion 2.4-12 fold. A 4-8 carbon chain would include alkane as well as alkenes. Applicants contention that the reference does not disclose alkene based compounds seem to refer to the lack of specific working examples for alkenes listed in table II. However, a working examples in the reference in no way reflect a limitation of the reference. The reference, generally teach that increasing the GRF hydrophobicity with 4-8 carbons, would make obvious an alkane or alkene having 4-8 carbons. Applicants have also argued unexpected result for alkenes over alkane in hydrophobicity, as indicated by the declaration by Dr. Brazeau. This declaration test the activity of GRF analogs substituted by Hexanoyl, Hexenoyl trans-2, and Hexenoyl trans 3 with the results demonstrated in Figure I of the specification. (It should be noted that though the declaration refers to Figures I and II for superior activity, only figure I demonstrates a comparative result.) The results disclosed in the specification do not indicate a superior activity for all of the alkenes encompassed by the claims. Note, in figure 1, the activity associated with Hexenoyl trans-2 (TT-01021) was similar to that of hexanoyl (TT-01015). Therefore, a it seems a superior activity is not associated with all of the alkenes encompassed by the claims. Indeed some of the alkenes have similar activity to their respective alkanes.

The references of Clark, Kann et al. and Recker all were cited to make obvious the method of treatments claimed for GRF analogs.

Rejections are maintained.

Double Patenting

8. Claims 1-19 remains and newly added claim 20 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of copending Application No. 08/702, 113.

It is noted that applicants request for abeyance until such time as one application is deemed allowable at which time a terminal disclaimer will be filed as appropriate. It is acknowledged that the applicants will submit a terminal disclaimer when one application is deemed allowable, such a disclaimer will be considered with submitted.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (703) 308-4001.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can normally be reached on (703) 308-0254. The fax phone number of this group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Anish Gupta


DOUGLAS W. ROBINSON
SUPERVISORY PATENT EXAMINER
GROUP 1800